REMARKS

Claims 1-16 are pending in the captioned application. In the outstanding Official Action, the Examiner has required restriction of claims 1-16 to one of following inventions under 35 U.S.C. §121:

Group I: Claim(s) 1-6, 8-12 and 16, drawn to a gene delivery system comprising a nucleotide sequence of interest to be delivered into a cell, the improvement which comprises a Relaxin-encoding nucleotide sequence to enhance a transduction efficiency of the nucleotide sequence of interest into the cell.

Group II: Claim(s) 14, drawn to a pharmaceutical composition for improving a penetration potency of a medicament into a tissue and for treating a disease or condition associated with accumulation of excess extracellular matrix, which comprises (a) a therapeutically effective amount of a Relaxin protein; and (b) a pharmaceutically acceptable carrier.

Group III: Claim(s) 7 and 13, drawn to methods of delivering a gene into cells and treating a cancer, the methods comprising administering a gene delivery system comprising a Relaxin-encoding nucleotide sequence.

PROVISIONAL ELECTION

Applicants provisionally elect Group III of claims 7 and 13 which are respectively drawn to a method for delivering a gene into cells comprising contacting the gene delivery system according to any one of claims 1-6 to a biosample containing cells and drawn to a method for treating a cancer comprising administering to an animal the pharmaceutical anti-tumor composition of claim 12, with traverse.

Applicants reserve the right to file a divisional application directed to the non-elected subject matter.

TRAVERSAL

Applicants respectfully traverse this restriction requirement because Groups I-III share a ***special technical feature*** under PCT Rule 13.2, and thus, all of the presently pending claims possess unity of invention. Accordingly, restriction is improper.

PCT Rule 13.2 states the following, in relevant part:

> "[T]he requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression 'special technical features' shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art."

In the present application, the special technical feature that is shared between Groups I to III is a "relaxin-encoding nucleotide sequence to enhance a transduction efficiency of a nucleotide sequence of interest into a cell." Such a special technical feature of the present invention is novel and inventive over the medical use of relaxin itself disclosed in *Conrad et al.* (US 2002/0019349) which the Examiner cited in the Official Action, thereby contributing to the prior art as a whole. *See* Written Opinion of The International Search Authority for the corresponding PCT application. In particular, Group I of claims 1-6, 8-12 and 16 are directed to a gene delivery system and a pharmaceutical composition which comprises said relaxin-encoding nucleotide sequence and thereby having an improved transduction efficiency, and Group III of claims 7 and 13 are directed to a gene delivery method and a cancer treatment method using the gene delivery system or the pharmaceutical composition claimed in Group I.

In view of the foregoing, Applicants respectfully submit that the claims of Groups I to III, particularly the claims of Groups I and II, possess "unity of invention" because

they share a special technical feature as required by PCT Rule 13.2. Thus, restriction of the claims of Groups I to III, is improper.

In addition, Applicants submit that the claims of Groups I to III should be examined together because, in addition to being improper on the basis of unity of invention, the restriction requirement omits "an appropriate explanation" as to the existence of a "serious burden" if a restriction were not required between the claims. Restriction/election between two groups of claims is only proper when (1) one group of claims is independent or distinct from another group of claims ***and*** (2) a "serious burden" exists on the examiner in examining both groups of claims. *See* MPEP § 803. A complete and thorough search for the inventions set forth in the Official Action would be coextensive. Thus, it would ***not*** be a ***serious*** burden upon the Examiner to examine all of the claims in this application.

Furthermore, Applicants have paid a filing fee for an examination of all the claims in this application. If the Examiner refuses to examine the claims paid for when filing this application and persists in requiring Applicants to file divisional applications for each of the groups of claims, the Examiner would essentially be forcing Applicants to pay duplicative fees for the non-elected or withdrawn claims, inasmuch as the original filing fees for the claims (which would be later prosecuted in divisional applications) are not refundable.

Accordingly, the Examiner is respectfully requested to reconsider and withdraw this restriction requirement.

CONCLUSION

In view of the foregoing, it is submitted that the Restriction Requirement is improper. Accordingly, the Examiner is respectfully requested to withdraw the requirement, and to examine all of the claims, namely claims 1-16, on the merits.

Applicants submit that the application is in condition for substantive examination. The Examiner is invited to contact the undersigned attorney if it is believed that such contact will expedite the prosecution of the application.

In the event this paper is not timely filed, Applicants petition for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

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